COLD-EEZE- zinc gluconate lozenge Mylan Consumer Healthcare, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts

Active ingredient (per lozenge)

Zinc Gluconate 2X HPUS[†] (2.3%) (13.3 mg zinc)

[†]The letters 'HPUS' indicate that the active ingredient is in the official Homeopathic Pharmacopeia of the United States.

Purpose

Cold Remedy

Uses

- reduces the duration of the common cold
- reduces the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness

Warnings

Do not use for treatment of influenza or allergies. This product is intended only to reduce the duration of the common cold and its symptoms.

Ask a doctor or pharmacist before use if you are taking minocycline, doxycycline, tetracycline or are on Coumadin (warfarin) therapy. Zinc treatment may inhibit the absorption of these medicines.

When using this product

- do not take on an empty stomach (to avoid possible minor stomach upset)
- it may cause a laxative effect

Stop use and ask your doctor if symptoms persist more than 7 days

If pregnant or breastfeeding,

ask a healthcare practitioner before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take one lozenge at the onset of symptoms
- dissolve entire lozenge in mouth
- do not chew
- do not swallow whole
- do not eat or drink for 15 minutes after use
- repeat every 2-4 hours until symptoms subside

Adults 18 years and over	do not exceed 6 lozenges per day
Children 12 to under 18 years	do not exceed 4 lozenges per day
Children under 12 years	ask a doctor before use

Other information

- store in a cool, dry place after opening
- best if used within 6 months after opening

Inactive ingredients

Acesulfame-K, glycine, isomalt, natural flavors

Questions or comments?

call 1-800-505-2653 (Mon – Fri: 8AM – 5PM EST)

*A clinical study found the Cold-EEZE formula reduces the duration of the common cold by 42%, when taken at the first sign of symptoms and used as directed.

The double blind placebo controlled study was conducted at the Cleveland Clinic and published in a peer reviewed journal.

For cold-fighting tips and more about the Cold-EEZE® science, go to www.ColdEEZE.com

[‡]Based on unit sales of cold shortening, homeopathic zinc lozenges.

This product has not been evaluated by the FDA.

Principal Display Panel - Sugar Free Cherry Lozenges

NDC 46017-324-25

The #1 Best Selling Zinc Lozenge Brand[‡]

Cold-EEZE®

ZINC GLUCONATE HOMEOPATHIC

SHORTENS YOUR COLD®

SUGAR FREE

CLINICALLY TESTED to Shorten Colds by 42%*

Pharmacist Recommended

NATURAL WILD CHERRY FLAVOR

25 Lozenges

- ✓ Our clinically tested formula releases zinc ions in the mouth[®] and shortens the duration of the common cold
- ✓ Take Cold-EEZE[®] at the first sign of a cold
- Continue until symptoms are gone
- ✓ Gluten Free
- No artificial colors or preservatives

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Inactive in gredients

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ZINC GLUCONATE HOMEOPATHIC

SHORTENS YOUR COLD



NATURAL WILDCHERRYFLAVOR

NDC 46017-324-25

The #1 Best Selling Zinc Lozenge Brand

COLD REMEDY

ZINC GLUCONATE HOMEOPATHIC

ZINC GLUCONATE HOMEOPATHIC

ZINC GLUCONATE HOMEOPATHIC



Principal Display Panel - Sugar Free Honey Lemon

NDC 46017-334-83

The Original and #1 Best Selling Zinc Lozenges*

Cold-EEZE®
ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD WORKS FASTER®+

SUGAR FREE

CLINICALLY PROVEN to reduce the duration of the common cold®+

#1 PHARMACIST RECOMMENDED

18 LOZENGES HOMEOPATHIC

RESEALABLE BAG INSIDE

NATURAL FLAVOR

Sugar Free Honey Lemon

- + Take Cold-EEZE® when you have a cold+
 + Continue until symptoms are gone*
- + Gluten Free
- + Our clinically proven formula releases zinc ions in the mouth that shorten the duration of the common cold⁺

No artificial colors or preservatives Acesulfame-K, glycine, Isomalf, natural flavors Inactive ingredients

- product may produce a laxative effect
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- gninago rafte artinom 8 nirtiw store in a cool, dry place after opening; best if used
 - · do not eat or drink for 15 minutes after use
 - stomach to avoid possible minor stomach upset do not take Cold-EEZE® lozenges on an empty Отлег інfогтайоп

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 - repeat every 2-4 hours as needed until all mouth (do not chew)
 - take Cold-EEZE® when you have cold symptoms
 completely dissolve a Cold-EEZE® lozenge in
 - Adults and children 12 years and over: Directions

reach of children.

healthcare practitioner before use. Keep out of If pregnant or breastfeeding, ask a

affect blood sugar levels Diabetic Warning: sugar replacements may is insufficient treatment for Influences or Allergies bne smolymyz ză bne bloo nommoo sett to noderub Cold-EEZE® lozenges are formulated to reduce the

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 - Ask a doctor before use if you Warnings

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sore throat, nasal congestion, post nasal drip

- reduces the severity of cold symptoms; cough, bloo nommon of the common cold

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Drug Facts

This product has no expiration date

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(M-R 8AM-5PMET) C9|| 1-800-202-5923 Questions or Comments:

go to www.ColdEEZE.com about the cold-EEZE® science, For cold-fighting tips and more

> Does Not Affect Blood Pressure Does Not Cause Light Headedness Does Not Cause Drowsiness

> > (збишем өөз)

medications and is gluten free. Cold-EEZE* is safe to take with most other

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of the common cold by almost half. Cold-EEZE* formula reduces the duration Clinical Studies have shown: The unique

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LOZENGES

Sugar Free Honey Lemon

ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD **WORKS FASTER®**

The Original and # Best Selling Zinc Lozenges*

ZINC GLUCONATE GLYCINE



Principal Display Panel - Sugar Free Pomegranate

NDC 46017-335-83

The Original and #1 Best Selling Zinc Lozenges*

Cold-EEZE®
ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD WORKS FASTER®+

SUGAR FREE

CLINICALLY PROVEN to reduce the duration of the common cold®+

#1 PHARMACIST RECOMMENDED

18 LOZENGES HOMEOPATHIC

RESEALABLE BAG INSIDE

NATURAL FLAVOR Sugar Free

Pomegranate

- + Take Cold-EEZE® when you have a cold+
 + Continue until symptoms are gone*
- + Gluten Free
- + Our clinically proven formula releases zinc ions in the mouth that shorten the duration of the common cold+

This product has no expiration date

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(M-F. 8AM-5PMET)

(see warnings)

C9|| 1-800-202-5223

Questions or Comments:

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ZINC GLUCONATE GLYCINE

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- product may produce a laxative effect
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- store in a cool, dry place after opening; best if used
- do not eat or drink for 15 minutes after use stomach to avoid possible minor stomach upset
- do not take Cold-EEZE*lozenges on an empty Other information

healthcare practitioner prior to use

and 4 lozenges for ages 12-17 Children under 12 years of age should consult a

- recommended daily dosage is 6 lozenges for adults apisqus smooduuks
 - lis linu babaan as zuon 4-2 yrava isagan •
 - mouth (do not chew)
 - completely dissolve a Cold-EEZE® lozenge in
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Drug Facts

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ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD

WORKS FASTER®

LOZENGES

Sugar Free Pomegranate

The Original and # Best Selling Zinc Lozenges*



COLD-EEZE

zinc gluconate lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:46017-324

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	Zinc Gluconate	2 [hp_X]

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
GLYCINE (UNII: TE7660XO1C)	
ISOMALT (UNII: S870P55O2W)	

Product Characteristics			
Color	WHITE (semi-translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	CHERRY	Imprint Code	Р
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46017-324- 25	1 in 1 BOX	06/12/2020	10/31/2022
1		25 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:46017-324- 83	1 in 1 BOX	10/11/2018	10/31/2022
2		18 in 1 BAG; Type 0: Not a Combination Product		
3	NDC:46017-324- 84	18 in 1 BAG; Type 0: Not a Combination Product	09/28/2018	10/31/2022
4	NDC:46017-324- 44	1 in 1 BOX	10/12/2018	10/31/2022
4		24 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
	09/28/2018	10/31/2022		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

COLD-EEZE

zinc gluconate lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46017-334
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	

GLYCINE (UNII: TE7660XO1C)	
ISOMALT (UNII: S870P55O2W)	

Product Characteristics			
Color	WHITE (semi-translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	HONEY (honey lemon)	Imprint Code	P
Contains			

P	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46017-334- 83	1 in 1 BOX	09/28/2028		
1		18 in 1 BAG; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved homeopathic		09/28/2018	10/31/2022	

COLD-EEZE

zinc gluconate lozenge

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46017-335	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients				
rength	Ingredient Name			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
	Glycine (UNII: TE7660XO1C)			
ISOMALT (UNII: S870P5502W)				
		ISOMALI (UNII: 5870P5502W		

Product Characteristics				
Color	WHITE (semi-translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	POMEGRANATE	Imprint Code	P	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46017-335- 83	1 in 1 BOX	09/28/2028		
1		18 in 1 BAG; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved homeopathic		09/28/2018	10/31/2022	
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Labeler - Mylan Consumer Healthcare, Inc. (831410522)

Revised: 10/2020 Mylan Consumer Healthcare, Inc.